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10/532,873	04/28/2005	Tetsuya Ishii	Q72768	2291

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EXAMINER	
REDDY, KARUNA P	

ART UNIT	PAPER NUMBER
1713	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,873	ISHII, TETSUYA	
	Examiner	Art Unit	
	Karuna P. Reddy	1713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *12 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to amendment filed on March 12, 2007. Applicants have amended claim 1; added claims 20-23. Claims 1-23 are pending.

2. In view of the amendment, previous rejection of claims 1-12 and 14-19 are withdrawn. However, the amendment necessitates new grounds of rejection for claims 1-12 and 14-19. The rejection of claim 13 is sustained. Claims 1-23 are pending.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 1, 3-5 and 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Ono et al (EP 0 507 160 A1).

Ono et al disclose an adhesive gel base comprising a water soluble high molecular weight substance and includes polyacrylic acid, a salt of polyacrylic acid. One or more kinds of water soluble high molecular weight substance are

used in the adhesive gel base. Water content is preferably in the range of 10 to 70% (page 3, line 16-27). The polyacrylic acid reads on carboxyvinyl polymer of claim 9. The water retaining agent used in the preparation prevents the volatilization of water contained in the adhesive gel base. The water retaining agent includes, for example, glycols, glycerin and reads on polyhydric alcohol of claim 1. An amount of the water retaining agent is preferably in the range of 1 to 70% (page 3, lines 29-35). See example 1 wherein the adhesive gel comprises aluminum hydroxide and polyacrylic acid in an amount of 0.3 parts and 2 parts respectively.

Therefore, Ono et al anticipate the instant invention.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1, 3-5, 7- 8, 10-11, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1 046 395 A1) in view of Ono et al (EP 0 507 160 A1).

Donati et al disclose a hydrogel mixture, containing sodium polyacrylate, polyhydrol such as sorbitol in the range of 40 wt% and water in the amount of 29.73 wt% (page 4, lines 8-35). The cross-linking agent preferably an aluminum compound is in a concentration of 0.01 to 3.0 wt% (page 3, lines 28-29). The composition further contains a pharmaceutically acceptable diclofenac salt (page 4, line 1). The hydrogel mixture preferably comprises a wetting agent chosen from polyhydric alcohols such as glycerol, propylene glycol, sorbitol etc (page 3, paragraph 0018) in a concentration of 5 to 70 wt% (page 3, paragraph 0019). The hydrogel mixture further contains a polymer compound such as polyvinyl pyrrolidine having high affinity for polyhydric alcohol in the amount of 2.0% and a pharmaceutically acceptable diclofenac salt (page 4, line1, 14).

The prior art of Donati et al differs from instant invention in the amount of water content in the composition.

However, Ono et al teach an adhesive gel base containing water content in a range of 10 to 70%. Water contained in the adhesive gel base increases swelling of the skin and permeability of the drug (page 3, lines 26-28). Therefore, it would have been obvious to one skilled in the art at the time invention was

made to use water content in the range of claim 1 of instant invention because Ono has proven successfully that permeability of drug increases at the said range of water content and one of ordinary skill in the art would expect the water content of Ono et al to work for the composition of Donati et al, motivated by expectation of success and thereby realize increased permeability of the drug.

8. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1 046 395 A1) in view of Ono et al (EP 0 507 160 A1) as applied to claim 1 above, and further in view of Yamazaki et al (JP 0 614 5049 A).

The discussion with respect to Donati et al in view of Ono et al in paragraph 7 is incorporated herein by reference.

The prior art of Donati et al in view of Ono et al are silent with respect to the usage of magnesium hydroxide aluminum hydroxide co-precipitate as a cross-linking agent.

However, aluminum magnesium hydroxide as a polyvalent metal salt is used as a cross-linking agent, to produce a cataplasm base having high tack and high base strength in a highly cross-linked state free from transfer of plaster to skin during peeling cataplasm, as taught by Yamazaki (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time invention was made to add magnesium hydroxide aluminum hydroxide to the composition of Donati et al in view of Ono et al to obtain the above mentioned advantages.

9. Claims 12, 15, 17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1 046 395) in view of Ono et al (EP 0 507 160 A1) as applied to claims above, and further in view of Bernstein (EP 95512 A) or LaHann (US 4,313,958).

The discussion with respect to Donati et al in view of Ono et al in paragraph 7 is incorporated herein by reference.

However, Donati et al in view of Ono et al are silent with respect to the addition of pharmaceutically active ingredient "capsaicin". However, capsaicin is a well known pharmaceutically active ingredient as taught by Bernstein, where in the composition is used to treat psoriatic skin (abstract). Furthermore, LaHann teaches the usefulness of "capsaicin" as a potent analgesic (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time invention was made to add "capsaicin" to the composition of Donati et al in view of Ono et al and thereby arrive at the claimed invention by realizing the above mentioned advantages.

10. Claims 2 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1 046 395 A1) in view of Ono et al (EP 0 507 160 A1) as applied to claim 1 above, and further in view of Sato et al (US 4,386,120).

The discussion with respect to Donati et al in view id Ono et al in paragraph 7 is incorporated herein by reference.

The prior art of Donati et al in view of Ono et al are silent with respect to the viscosity of (meth)acrylic acid-base polymer in aqueous solution.

However, Sato et al teaches the formulation of easily water soluble sodium polyacrylate where in the viscosity of the solution is 50 - 700 c.p.s (column 5, lines 26-28). Therefore, it would have been obvious to one skilled in art at the time invention was made to use sodium polyacrylate in aqueous solution with viscosity of 50-700 c.p.s as taught by Sato in the composition of Donati et al in view of Ono et al since a species of a genus will work properly, motivated by expectation of success.

11. Claim 13 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1 046 395 A1).

The rejection is adequately set forth in paragraph 9 of the previous office action and is incorporated herein by reference.

12. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1 046 395 A1) in view of Ono et al (EP 0 507 160 A1).

Donati et al disclose a process for the preparation of hydrogel mixture consisting of thickening agent (sodium polyacrylate), wetting agent (polyhydric alcohols), cross-linking agent (Al compound) and water by mixing these and other optional ingredients in several stages. The process consists of adding polyhydric alcohol or wetting agent (sorbitol) to water. To this aqueous solution is added, in the form of aqueous solution, one half the quantity of cross-linking agent (dihydroxy aluminum glycinate), thickening agent (sodium polyacrylate). To this mixture thus obtained is added an aqueous mixture of optional ingredients

such as polyvinyl pyrolidine, (page 3, paragraph 0027; page 4, paragraph 0028-0030). Finally, an aqueous solution consisting of remaining parts of crosslinking agent, thickening agent and the active pharmaceutical agent are added.

The prior art differs with respect to water content in the final composition and sequence of process steps.

However, the composition is substantially similar to that of the prior art though the sequence of mixing components differs. Therefore, it would have been obvious to one skilled in art at the time invention was made to alter the sequence and essentially arrive at the instant claim, absent evidence of unexpected results. See In re Burhans, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results); In re Gibson, 39 F.2d 975, 5 USPQ 230 (CCPA 1930) (Selection of any order of mixing ingredients is prima facie obvious.).

As to the water content, prior art of Donati et al does not preclude using water content of the instant invention. Furthermore, Ono et al teach an adhesive gel base containing water content in a range of 10 to 70%. Water contained in the adhesive gel base increases swelling of the skin and permeability of the drug (page 3, lines 26-28). Therefore, it would have been obvious to one skilled in the art at the time invention was made to use water content in the range of claim 21 of instant invention because Ono et al has proven successfully that permeability of drug increases at the said range of water content and one of ordinary skill in

the art would expect the water content of Ono et al to work for the final composition of Donati et al in view of Ono et al, motivated by expectation of success and thereby realize increased permeability of the drug.

13. Claims 21 and 22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1046395) in view of Sato et al (US 4,386,120).

Claims 21 and 22 are the same as previously presented claims 2 and 14 respectively. The rejection is adequately set forth in paragraph 6 of the previous office action and is incorporated herein by reference.

14. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Donati et al (EP 1 046 395 A1) in view of Sato et al (US 4,386,120) as applied to claim 21 above, and further in view of Bernstein (EP 95512 A) or LaHann (US 4,313,958).

The discussion with respect to Donati et al in view of Sato et al in paragraph 13 is incorporated herein by reference.

The prior art of Donati et al in view of Ono et al and Sato et al are silent with respect to the addition of pharmaceutically active ingredient "capsaicin".

However, capsaicin is a well known pharmaceutically active ingredient as taught by Bernstein, where in the composition is used to treat psoriatic skin (abstract). Furthermore, LaHann teaches the usefulness of "capsaicin" as a potent analgesic (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time invention was made to add "capsaicin" to the

composition of Donati et al in view of Ono et al and Sato et al and thereby arrive at the claimed invention by realizing the above mentioned advantages.

Response to Arguments

15. Anticipation rejection over Kuroya et al, anticipation rejection over Donati et al and obviousness rejection over Donati et al in view of Yamazaki et al are moot in view of the amendments and new grounds for rejection.

16. In response to obviousness rejection of claim 13 over Donati et al, applicant's argue that the process step of adding polyhydric alcohol to (meth)acrylic acid-base polymer solution with a water content of 50 % or more results in the polymer not getting aggregated. Examiner maintains the rejection because there is no suggestion to this aspect of the process either in claim language or in the specification. Furthermore, specification discloses aggregation of polymer in reference to the ratio of acrylic acid and acrylate in acrylic acid-acrylate copolymer.

17. In response to obviousness rejection of claims 12, 15, 17 and 19 over Donati et al (EP 1046395) in view of Benstein (EP 95512A) and LaHann (US 4,313,958), applicant's argue there is no indication in the prior art of Donati et al that capsaicin is interchangeable with Diclofenac. Examiner maintains that replacing one pharmaceutically active ingredient with another pharmaceutically active ingredient is within the scope of skilled artisan.

18. In response to obviousness rejection of claims 2 and 14 over Donati et al (EP 1046395) in view of Sato et al (US 4,386,120), applicants argue the range of viscosity 50 to 700 c.p.s is used only for spraying. However, neither the claim language nor specification excludes the usage of composition of instant claim for spraying. Applicants further argue Sato's does not describe plasters. It is held by court that it is not necessary for the references to be physically combinable. See In re Sneed, 710 F.2d 1544, 1550, 218 USPQ 385, 389 (Fed. Cir. 1983) ("[I] it is not necessary that the inventions of the references be physically combinable to render obvious the invention under review.")

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will

the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karuna P. Reddy whose telephone number is (571) 272-6566.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karuna P Reddy
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